

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Wednesday, December 06, 2006

MEMORANDUM

Subject:

Acute Toxicity Review for EPA Reg. No.: 71654-9/ CDRW-D5

DP Barcode: D333757

To:

Emily Mitchell, PM 32/ Wanda Henson

Regulatory Management Branch Antimicrobials Division (7510C)

From:

Ian Blackwell, Biologist

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Through:

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Antimicrobials Division (7510C)

Applicant:

E.I. DuPont de Nemours and Company

FORMULATION FROM LABEL:

Active Ingredient(s):

Sodium dichloro-s-triazinetrione

Other Ingredient(s):

Total:

% by wt.

15

85

100.00

- 1) <u>BACKGROUND</u>: The registrant has submitted an attrition and particle-size analysis to support a request for the waiver of the acute inhalation toxicity study for their product. The waiver request is presented in MRID Number 469384-01. The premise for the waiver of these studies is:
 - a) This report discusses particle size distribution and an attrition study of the product. No acute inhalation toxicity study was conducted.
 - b) The study began with freshly produced product (manufactured that day). The first day was considered "Time 0".
 - c) The registrant had samples of the product commercially shipped twice.
 - d) Three samples of each of the two product sets (b and c above) were assessed for particle size.
 - e) The registrant's 9/19/06 supplement requests a toxicity category III.

CTT/PSB will combine the results of this assessment with the results of the 6/30/2005 CTT/PSB review of 71654-9.

2) RECOMMENDATIONS: PSB findings are:

a) CTT/PSB waives the acute inhalation toxicity study for Registration Number 71654-9. Agency guidelines state that, for acute inhalation toxicity waivers based upon particle size, samples must show no more than 1% of particles are less than 100 microns (μ m). This attrition study does not *quite* meet these standards; it is true that less than 3% of the particles in this study are lower than 100 μ m. CTT/PSB will combine this information with a knowledge of the results of the other acute toxicity studies (of 71654-9) and other acute inhalation toxicity waivers for products containing this active ingredient.

The acute toxicity profile for Registration Number 71654-9 is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	465369-01	III	Acceptable
Acute Dermal Toxicity	465369-02	IV	Acceptable
Acute Inhalation Toxicity	469384-01	III	Waived
Primary Eye Irritation	465369-04	I	Acceptable
Primary Skin Irritation	465369-05	II	Acceptable
Dermal Sensitization	465369-08	Sensitizer	Acceptable

3) LABELING:

a) The signal word is "DANGER" based upon the results of the primary eye irritation study.

b) The Precautionary Statements should state:

"Corrosive. Causes irreversible eye damage and skin irritation. Harmful if swallowed or inhaled. Do get in eyes, on skin, or, on clothing. Avoid breathing dust, vapor, or, spray mist. Wear protective eyewear such as goggles, face shield or safety glasses. Wear protective clothing and chemical-resistant gloves. When mixing and loading, wear a chemical-resistant apron. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals."

c) The First Aid statements must state:

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for treatment advice.

If Inhaled:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
- Call a Poison Control Center or doctor for treatment advice.

If on Skin or Clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center or doctor for treatment advice.

If Swallowed:

- Call a Poison Control Center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the Poison Control Center or doctor.
- Do not give anything by mouth to an unconscious person.

- d) This product meets the criteria for Restricted-Use classification based on data that place it in toxicity category I for primary eye irritation. In lieu of assigning the product Restricted-Use classification, the Product Manager may consider requiring alternative labeling for face shield, goggles, safety and/or gloves (to mitigate the identified hazards).
- e) This product meets the Agency criteria for Child-Resistant Packaging (CRP) based upon data placing it in toxicity category I for primary eye irritation. Products that are assigned Restricted-Use status are not *also* required to be placed in CRP.

[&]quot;Probable mucosal damage may contraindicate the use of gastric lavage."

ACUTE INHALATION TOXICITY WAIVER (§81-3, 870.1300)

Product Manager: 32 Reviewer: I. Blackwell

MRID No.: 469384-01 Study Completion Date: 8/30/2006

Lab Study No.: DCSE-2006-012

Testing Laboratory: DuPont Center for Analytical Services (CCAS)

Author: Edward B. Lightcap

Quality Assurance (40 CFR §160.12): Not applicable

Test Material: CDRW-D5

Concentration: 100% (This is a particle analysis.)

Species: No animals were tested

Weight: Males= n/a Females= n/a

Age: n/a Source: n/a

Table 1.

Particle Size Assessment – Time Point Zero					
Point	Bag	Test Tube	% < 9.8 μm	9.8 < % < 101.1 μm	
Time 0 A	Α	A01	0.32	2.56	
		A05	0.33	2.62	
		A09	0.33	2.62	
		A13	0.33	2.62	
С	A03	0.33	2.68		
	A07	0.34	2.71		
	A11	0.34	2.61		
	A15	0.33	2.71		
	A02	0.34	2.71		
	A06	0.34	2.74		
		A10	0.34	2.74	
	SAME.	A14	0.34	2.74	

Table 2

Particle Size Assessment – Twice Commercially Shipped						
Point	Bag	Test Tube	% < 9.8 μm	9.8 < % < 101.1 μm		
2x Shipped A B C	Α	A01	0.34	2.80		
		A05	0.33	2.77		
		A09	0.34	2.77		
		A13	0.32	2.62		
	В	A03	0.34	2.72		
		A07	0.34	2.73		
		A11	0.33	2.61		
		A15	0.34	2.71		
	С	A02	0.34	2.82		
		A06	0.34	2.78		
		A10	0.33	2.73		
		A14	0.34	2.80		